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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 02/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.
09/927,788

Applicant(s)
Mahan et al

Examiner
Partner

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 22, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-9, 12, 13, 15, 18, 20, 22, 30, and 31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 12, 13, 15, 18, 20, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-4, 7-9, 12, 13, 15, 18, 20, 22, 30, and 31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

New claims 30-31 have been added.

Claims 1,3-4,7,18 have been amended.

Claims 1-4, 7-9, 12-13, 15, 18, 20, 22 and 30-31 are pending.

Claim 5 has been canceled; Claims 6,10-11,14,16-17, 19, 21 and 23-29 were previously canceled

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

2. Newly submitted claims 30-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

All of the previously examined claims were directed to species of invention associated with pathogenic microorganisms. No claims were examined directed to an immunogenic composition that expresses a heterologous tumor antigen; thus defining a species of invention that is independent and distinct from those previously examined in the first action. Claim 30 is directed to a species of invention not previously examined.

Additionally no eukaryotic expression systems were examined, only expression cassettes inserted into live bacteria were previously examined. Claim 31 recites a species of expression cassette, which is specific species that defines an independent and distinct invention but has not been previously considered on the merits in the first Office Action.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Objection and Rejection Withdrawn

3. The disclosure objected to because of the following informalities: At page 17, paragraph 0067 an image of a “hand” is recited. At page 18, paragraph 0068 an image of a “hand” is recited. At page 70, Table 1, just before paragraph 0248 an image of a “lined page” is recited. In light of the amendment of the specification to clarify the informalities..

Claim 1 rejected under 35 U.S.C. 112, second paragraph for reciting the phrases “live bacteria” and “unaltered pathogenic bacteria”, in light of the amendment of the claim to define the live bacteria to be an attenuated form of the wild type of the live bacteria.

Claim 3 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “wherein the Dam activity is altered by a second heterologous nucleotide sequence” in light of claim 3 having been amended to the phrase --further comprises-- “

Claim 4 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “wherein the first heterologous sequence is operatively inserted into a first expression cassette”, in light of the amendment of claim 4 to define the first heterologous sequence to be plasmid associated.

Claim 5 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “operatively inserted into a second expression cassette”, in light of claim 5 having been canceled.

Claim 7 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “wherein the genetically engineered change”, in light of the amendment of the claim to define the attenuation to be a change in the DNA of the live bacteria of claim 1.

Claim 18 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “sexual transmitted disease”, in light of the amendment of the claim to recite the term --sexually--.

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Rejections Maintained

4. Claims 1-4, 7-9, 12-13, 15, 18, 20 and 22 under 35 U.S.C. 102(e) as being anticipated by Curtiss, III et al (US Pat. 6,383,496), for reasons of record in paper number 14, and arguments set forth below in response to Applicant's traversal of the applied Curtiss, III et al reference.

Response to Arguments

5. The rejection of claims 1-4, 7-9, 12-13, 15, 18, 20 and 22 under 35 U.S.C. 102(e) as being anticipated by Curtiss, III et al (US Pat. 6,383,496) is traversed on the grounds that:

a. "The cited reference (Curtiss) is not "prior art" for the following reasons:

i. Priority is claimed in the instant Application providing priority back to February 2, 1999 and the Curtiss patent US 6,383,496 is a CIP of 08/970,789 which does not include any disclosure related to the *dam gene*.

6. It is the position of the examiner that the instantly claimed invention of independent claim 1, does not require the alteration to be in the dam gene, but the attenuated live bacteria must only evidence a **different phenotypic activity** based upon altered DAM activity; the dam gene used to traverse the applied reference is not recited in the claims. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

In support of the examiner's position, Torreblanca et al (1996) is being cited as evidence that an aro gene mutation alters DAM activity, specifically an aroB mutant strain of Salmonella

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evidenced a dam (-) phenotype, as the strains are leaky (see page 18, col. 2, paragraph 5, first half of paragraph).

Curtiss, III et al (US 6,383,496), claims a genus of *aro gene* mutant live attenuated strains of bacteria, which would include *aroA*, *B*, *C* and *D* genes of Salmonella. The priority document for US 6,383,496, is issued patent US Pat. 6,024,961 which discloses and claims *aro gene* mutants and provides sufficient priority for the Curtiss, III (US 6,383,496) for application of '496, to the instantly claimed invention.

Curtiss, III et al (US 6,383,496), as evidenced by Torreblanca et al, would inherently have altered DAM activity, due to mutations in the aro genes. ^{claims 27, 19, 12} Clearly Curtiss, III et al (US 6,383,496) evidences support and priority for mutants with altered DAM activity, wherein the altered activity is the result of mutations in other genes that effect phenotypic DAM activity.

Despite the fact that the reference does not discuss DAM activity, the mutants claimed would evidence altered DAM activity based upon mutations introduced into other genes in the bacterium. In addition to aro gene mutations, additional mutations in *pab*, *pur*, *asd*, *dap*, *nadA*, *pncB*, *galE*, *pmi*, *fur*, *rpsL*, *ompR*, *htrA*, *hemA*, *cdt*, *cya*, *crp*, *phoP*, *phoQ*, *rfc*, *poxR*, *galU* could also effect the over all activity of DAM (see Heithoff et al (1999, page 969, col. 2, second half of first paragraph, states that it is possible that PhoP (-) strains have different amounts of DAM activity.)

Therefore, Curtiss, III et al, (US 6,383,496) discloses, and claims live attenuated strains of Salmonella bacteria that inherently evidence altered DAM activity and comprise first and second

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heterologous nucleotide sequences, specifically one being a coding heterologous nucleotide sequence for a heterologous antigen for a pathogen, specifically a virus, bacterium, protozoan or fungus (see Curtiss III, et al, priority document '961, claims 19, 34-38), another heterologous nucleotide sequence that inactivates at least an *aro* gene, or *phoP* gene, by insertion (support in priority document '961, col. 8, lines 52, 58 and 60) that inherently alters DAM activity (as evidenced by Torreblanca et al (1996) or Heithoff et al (1999)), as well as the insertion of a recombinant *rpoS*⁺ nucleotide sequence into the live attenuated bacterium; the *rpoS* gene altering the activity and growth of the cell, thus altering the phenotype and activity of Dam .

Curtiss, III teaches the utilization of a plurality of plasmids for the attainment of the live, attenuated, mutant strains of bacteria that comprise a mutation that alters Dam activity (relative to the wild type strain that is unaltered), expresses a heterologous antigen, and also comprises an *rpoS*⁺ recombinant gene that alters cell function and therefore alters Dam activity. Utilization of more than one plasmid to produce the live attenuated strains is disclosed, the plasmid encoded heterologous nucleotide sequences being the heterologous coding sequence for a heterologous antigen, and the coding sequence of the *RpoS* allele (see priority document '961, col. 7, line 58; col. 14, line 67 though col. 15, line 1; col. 11, lines 7-30).

The rejection is maintained for reasons of record in paper number 14, and arguments set forth above. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or

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of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 sets forth that the second nucleotide sequence is what alters Dam activity, but the composition of claim 1 does not provide antecedent basis for the word "second". If the second sequence is essential for alteration of Dam activity, and is not recited in claim 1, then an essential reagent is missing from claim 1, in light of the claim limitations newly set forth in amended claim 3. Clarification is requested.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp February 11, 2003


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